

REMARKS

Status of the Claims

Claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60, and 105-124 are currently pending in the application.

Claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60, and 105-124 remain under consideration with entry of this Response.

Summary

Claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60, and 105-124 are pending in the application and were examined in the Office Action dated 24 April 2008. Applicants note with appreciation that the following rejections have been withdrawn by the Office: **(i)** the rejection of claims 2, 7-23, 29-34, 36, 38-39, 44-45, 47-56, 59-60 and 105-124 under 35 U.S.C. §103(a) as unpatentable over International Publication No. WO 02/38185 to Dunn et al. (“Dunn”); **(ii)** the rejection of claims 24-26, 46, 55 and 56 under 35 U.S.C. §103(a) as unpatentable over Dunn in view of International Publication No. WO 00/74650 to Brodbeck et al. (“Brodbeck1”); and **(iii)** the rejection of claims 122-124 under 35 U.S.C. §103(a) as unpatentable over Dunn in view of U.S. Patent No. 6,130,200 to Brodbeck et al. (“Brodbeck2”).

However, the following new grounds of rejection have been entered: **(a)** claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60 and 105-124 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite; **(b)** claims 2, 9-26, 29-34, 36, 38-39, 46-56, 59, 105-116, and 119-124 have been rejected under 35 U.S.C. §103(a) as unpatentable over Brodbeck2; and **(c)** claims 7-26, 29-34, 36, 38-39, 44-56, 59-60, and 105-124 have been rejected under 35 U.S.C. §103(a) as unpatentable over Brodbeck2 in view of Dunn. Applicants respectfully traverse all pending claim rejections for the following reasons.

The Rejection under 35 U.S.C. §112, Second Paragraph

Claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60 and 105-124 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. In particular, the Office has objected that “it is unclear what consistencies are ‘gel-like’ [and asks] how do ‘gel-like’ consistencies differ from ‘gel’ consistencies.” Office Action at page 2. Applicants respectfully traverse the rejection for the following reasons.

The fundamental issue regarding compliance with the requirement for definiteness under 35 U.S.C. §112, second paragraph, is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and precision. As stated in Section 2173.02 of the MPEP, the relevant inquiry must therefore assess claim language, not in a vacuum, but in light of: (a) the content of applicants’ disclosure; (b) the teachings of the prior art; and (c) the claim interpretation that the ordinarily skilled person in the relevant art would give. The mere use of relative language, including terms of degree, does not automatically render the claim indefinite under Section 112, second paragraph. *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends instead upon whether or not the skilled person would understand what is claimed, in light of the specification. MPEP §2173.05(b). Furthermore, a fundamental principal of 35 U.S.C. §112, second paragraph, is that applicants are their own lexicographers and may define their claims in whatever terms they choose as long as the terms are not used in ways that are contrary to accepted meanings in the art. For this reason, a claim may not be rejected solely because of the type of language used to define the recited subject matter. *In re Swinehart*, 160 USPQ 226 (CCPA 1971).

In the instant rejection, the Office has asked if there is any difference between a “gel-like” consistency and a “gel” consistency. Applicants submit that the Office has answered its own question, that is, there is obviously no difference at all. Accordingly, when the relevant skilled person, who in this case is a pharmaceutical formulation chemist with a reasonable university education as well as likely having a post-graduate education, is asked what a “gel-like” consistency is, that person would have no hesitation

in answering that the consistency is “like a gel” (not like a “solid”, and not like a “liquid”).

Accordingly, since the skilled person would clearly understand what a “gel-like” consistency circumscribes, even without the benefit of the teachings provided by applicants’ specification, simple common sense, and the pharmaceutical formulation experience that the skilled person has readily at hand, the instant rejection is improper. Reconsideration and withdrawal of the rejection of claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60 and 105-124 under U.S.C. §112, second paragraph, is thus earnestly solicited.

The Rejections under 35 U.S.C. §103(a)

Claims 2, 9-26, 29-34, 36, 38-39, 46-56, 59, 105-116, and 119-124 have been rejected under 35 U.S.C. §103(a) as unpatentable over Brodbeck2. In particular, the Office asserts that Brodbeck2 teaches compositions having similar components to applicants’ recited compositions, but then acknowledges that Brodbeck2 fails to teach: the specific polymer molecular weights required by applicants’ claims; the specific solvents required by applicants’ claims; and the specific short term duration (7 day or less delivery of the beneficial agent) again as required by applicants’ claims. Office Action at page 3. Nevertheless, the Office concludes that “it would have been obvious” to use all of applicants’ recited elements even though Brodbeck2 fails to teach them, and further that “there is a reasonable basis to conclude that Brodbeck2’s product would be capable of delivering beneficial agent over less than seven days.” Office Action at page 4. Applicants respectfully traverse the rejection.

The Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a). *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). According to the Federal Circuit, “the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.” *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

In the present rejection, the Office has conceded that every single core element recited in applicants' claims is missing from the Brodbeck2 disclosure. In particular, applicants have disclosed and claimed novel and unique pharmaceutical depot compositions that have the benefit of providing for very short term delivery of a beneficial agent. Applicants have disclosed and claim that these formulations are produced using a unique combination of polymers and solvents that are specially selected to provide the short term duration. However, the Office somehow concludes that even though all of these elements are missing from Brodbeck2, they would somehow necessarily be present in some Brodbeck2 compositions. In other words, the Office seeks to provide all of the missing disclosure from Brodbeck2 by way of a theory of inherency.

However, applicants note that the burden of proof for any assertion of inherency is exceptionally high. The fact that a certain result or characteristic may occur, or may be present in the prior art is simply not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), emphasis added.

In the instant case, the Office has merely argued that 7 day or less duration compositions may result from Brodbeck2's disclosure and further that even though applicants' specifically recited polymer and solvent selections are not disclosed by Brodbeck2, these components may fall under the general disclosure of the other solvents and polymers that Brodbeck2 did disclose. These assertions clearly fail to establish the Office's burden of inherency from Brodbeck2. The Office has simply failed to identify

that all of the specific missing elements from Brodbeck2 would somehow inherently still be there and would further be understood by the skilled person.

In other words, the Office has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), since it has not shown by clear and convincing evidence that a person of ordinary skill in the art would have recognized that Brodbeck2 disclosed 7 day or less implant systems, containing applicants' expressly recited solvent and polymer components, and further that the skilled person would have had a reasonable expectation of success in creating such systems. Accordingly, the rejection of claims 2, 9-26, 29-34, 36, 38-39, 46-56, 59, 105-116, and 119-124 under 35 U.S.C. §103(a) as obvious over Brodbeck2 is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

Claims 7-26, 29-34, 36, 38-39, 44-56, 59-60 and 105-124 stand rejected under 35 U.S.C. §103(a) as unpatentable over Brodbeck2 in view of Dunn. In particular, the Office has relied upon its theory of inherency over Brodbeck2 as discussed immediately above, and further acknowledges that the mixture of benzyl alcohol and benzyl benzoate is also lacking from Brodbeck2. Office Action at page 5. The Office then asserts that Dunn teaches "an injectable implant device comprising a beneficial agent, a PLGA polymer, and a solvent, wherein solvents such as benzyl alcohol, benzyl benzoate and combinations thereof are useable." Office Action at page 5. The Office then concludes "it would have been ... obvious ... to use the solvents of [Dunn]" since "the solvents of [Dunn] are used for the same type of implant as those of Brodbeck2." Office Action at page 5. Applicants respectfully traverse the rejection for the following reasons.

Applicants note that this new ground of rejection is substantially identical to the Section 103 rejections that have been withdrawn, wherein the Office has asserted that the skilled person would use teachings from Dunn's solid implant technology to modify compositions from Brodbeck2's gel implant technology. As demonstrated in the Response submitted 21 October 2008, this combination is improper since the two systems are fundamentally different, and the skilled person would know that use of one technology to modify the other would render that technology unfit for its intended purpose.

As demonstrated herein above, Brodbeck2 fails to teach every core element of applicants' recited compositions, and the Office's theory of inherency over Brodbeck2 is simply not supported by any reading of that reference. In addition, the Office's proposal that the skilled person would look to Dunn's solid implant technology to find a suitable solvent combination to make a non-solid (gel) implant system is also not supportable. Modifying Brodbeck2 to provide Dunn's solid implants would render Brodbeck2's implants inoperable, frustrating the intended purpose of those systems. This is strong evidence of nonobviousness as noted by the Supreme Court in *KSR* emphasizing that consideration of prior art that teaches away from the claimed invention is also relevant to the determination of obviousness. In particular, the Court stated that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). See also, *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, where the Federal Circuit stated that "[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references.' *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 80 U.S.P.Q.2d 1641, 1646 (Fed. Cir. 2006), citing *In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004) (emphasis added). Finally, as stated in the MPEP, "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. M.P.E.P § 2143.01. The Federal Circuit has stated a similar principle in *In re Gordon*, indicating that where the proposed modification would render the prior art invention unsatisfactory for its intended purpose, the prior art invention effectively teaches away from the proposed modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

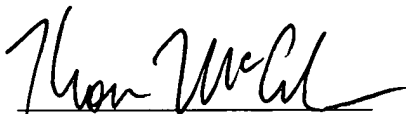
Since Brodbeck2 fails to teach or suggest every single one of the core elements of applicants' recited compositions, and since modification of Brodbeck2's gel systems with Dunn's solid implant systems as proposed by the Office would further render the Brodbeck2 systems inoperable, the rejection of claims 7-26, 29-34, 36, 38-39, 44-56, 59-

60 and 105-124 under 35 U.S.C. §103(a) as unpatentable over the combination of Dunn and Brodbeck2 is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

Respectfully submitted,



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Date: 3 March 2009

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